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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,826	10/15/2001	George Goicoechea	BSI-010US4	4645

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07/03/2003

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 07/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,826

Applicant(s)

GOICOECHEA ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20,22-41,43-49 and 54-62 is/are pending in the application.
- 4a) Of the above claim(s) 26,34-38,40 and 58-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,22-25,27-33,39,41,43-49 and 54-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Applicant's election of Group I (stents) and suture connection species (claims 32-33) in Paper No. 5, and furthermore species A (figures 1-4) in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 26,34-38, and 58-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No's. 5 and 7.

Priority

3. This application lacks the necessary reference to the four prior applications. A statement listing all continuing data should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 20,22-25,27-33,39,41,54,55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6,8-14,20,23 of U.S. Patent No. 5,800,508. Although the conflicting claims are not identical, they are not patentably distinct from each other because each set of claims defines structurally equivalent stents.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the specification does not describe the suture as a thermoplastic tied loop.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 3, "an additional stent segment" is unclear whether reference is made to previously recited first or second stent segments or a new segment.

Claim Objections

10. Claims 20,22-25,27-30,39,54-56 are objected to because of the following informalities:

Claim 20 is objected to because of the limitation "additional stent segments". The limitation implies stent segments were previously defined, but claim 54 lacks any stent segment description. Examiner suggests Applicant to amend claim 54 to be a stent comprising at least one stent segment which further comprises plurality of hoops aligned..." Claims 22-25,27-30 are objected to for depending on an objected claim.

Claim 39 is objected to because "square" is unclear. Examiner suggests replacing square with perpendicular.

Claim 54 (line 6), 55 (line 7), and 56 (lines 2,5) are objected to because "the axis" is unclear. Examiner suggests changing to "the longitudinal axis" (of the stent).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 20,22-24,31-33,41,54,55 are rejected under 35 U.S.C. 102(e) as being anticipated by Cragg US PN 5,405,377.

Cragg discloses in figures 1-4 and line 40 of col. 2 through line 4 of col. 3 a stent 10 comprising a plurality of hoops 11 formed from a continuous Nitinol wire comprising pairs of elongate elements forming apices abutting apices of adjacent hoops, which are connected by thermoplastic suture material 12. All hoops are axially aligned and of equal diameter.

13. Claims 20,22-24,31,54-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Fontaine US PN 5,370,683.

Fontaine discloses in figures 6, 9, 10, and 14 a stent comprised of a continuous wire formed into a plurality of interconnected (by welding lines 11-13 of col. 6) hoops at abutting apices or vertices (5,5' and 7,7') formed by pairs of elongate elements within

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each hoop. All hoops are axially aligned and of equal diameter. Lines 42-56 of col. 4 describe the vertices pointing in an axial direction and lying in a common plane perpendicular to the longitudinal axis of the stent.

14. Claims 20,22-25,31,32,39,54-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Maeda et al. US PN 5,800,456.

Maeda et al. discloses in figures 3-8 and abstract a stent comprised of a continuous wire formed into a plurality of interconnected hoops at apices 8 formed by pairs of elongate elements 13,15 within each hoop. The apices are connected by suture material 32. All hoops are axially aligned and of equal or different diameter (see abstract). Lines 42-56 of col. 4 describe the vertices pointing in an axial direction and lying in a common plane perpendicular to the longitudinal axis of the stent. Figure 8 shows the longitudinal ends of the stent being square to the long axis of the stent.

15. Claims 20,22-25,39,43,44,47,54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff US PN 5,104,404.

Wolff discloses in figures 1 and 6 a stent comprised of a plurality of hoops 12 interconnected at apices formed by pairs of elongate elements within each hoop. Securing means 14 connects the apices of adjacent hoops. All hoops are axially aligned and of equal or different diameter (figure 6). Figure 1 shows the longitudinal ends of the stent being square to the long axis of the stent. As shown in Figure 1, each

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end portion of the stent, left 12 or right 12, may have a tubular coating of radiopaque material over element 14 (see lines 63-65 of col. 3).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 45,46,48,49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff US PN 5,104,404 as applied to claims 54,43,44,47 above, and further in view of Piplani et al. US PN 5,824,039.

Wolff discloses the use of radiopaque markers in the form of tubes but does not expressly disclose the use of gold or platinum as the material or that the marker may be a wire. Piplani teaches a stented vascular graft having gold and platinum markers as well as markers in the form of wires (see lines 22-26 of col. 5 and lines 14-17 of col. 7) in order to provide visibility under fluoroscopy during implantation of the device.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the stent disclosed by Wolff to include gold or platinum as the material or to provide the marker in the form of a wire as taught by Piplani et al. in order to provide sufficient visibility under fluoroscopy during implantation of the device.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

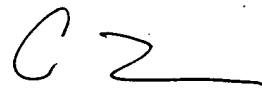
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM

June 28, 2003



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